

REMARKS

Claims 1-2 are allowed. Claim 3 is amended. Support of the amendments can be found in lines 18-29 on page 8 of the specification (see also paragraph [0052] of US 2007/0275419). No new matter is added.

Claim Rejections - 35 USC § 112

On page 3, section 7 of the Office Action, the Examiner rejects Claims 3-8, 14 and 15 under 35 USC §112, second paragraph as being indefinite. The Examiner sets forth two grounds of rejections: (a) antecedent basis for “polynucleotide;” and (b) “such as” language for hybridization conditions

Rejection Regarding Antecedent Basis for the Phrase “Polynucleotide”

Specifically, the Examiner states the following:

a) Claims 3-8, 14 and 15 recite the limitation “polynucleotide” in the preamble and in element c) of Claim 3, and Claims 4-8, 14 and 15 recite or incorporate “the polynucleotide of Claim 3”. Claim 3 also recites “a nucleotide” in elements a) and b). It is unclear if Claims 4-8, 14 and 15 are only referring to the polynucleotide in element c) of Claim 3 or whether the intended scope is for the nucleic acids of elements a)-c) of Claim 3 as referred to as the “polynucleotide” in the preamble. In other words, which of the two antecedent “polynucleotide” in Claim 3 are being referred to by Claims 4-8, 14 and 15? (emphasis added).

Claim 3 as amended replaces the phrase “polynucleotide” with the phrase “nucleotide sequence” in prong (c). Because the amendment does not “change the disclosure in a way contrary to its substance as filed,” *Tandon Corp. v. Int’l Trade Comm’n*, 821 F.2d 1017 (Fed. Cir. 1987), Applicants respectfully request the withdrawal of the rejection regarding antecedent basis for the phrase polynucleotide.

Rejection Regarding the Phrase “Such As” for Hybridization Conditions

Specifically, the Examiner states the following:

b) Claims 3-8, 14 and 15 are indefinite for the recitation “hybridizes under stringent conditions” in element c) of Claim 3 because the exact conditions are not defined in the claims or the specification. Applicants point to the specification at [0052] for defining the meaning of the phrase. It is noted that even the specification uses indefinite language, i.e., “such as”, to describe a “stringent condition”. Applicants are requested to further clarify the meaning of “stringent condition”. (emphasis added).

To expedite the prosecution of the above referenced application, Claim 3 as amended recites two hybridization conditions based on lines 18-29 on page 8 of the specification (paragraph [0052] of US 2007/0275419).

In light of the amendments made to prong (c) of claim 3, Applicants respectfully request withdrawal of the rejection regarding the phrase “such as” for hybridization conditions.

Written Description

On page 4, section 8 of the Office Action, the Examiner rejects Claims 3-8, 14, and 15 as failing to comply with the written description requirement.

Specifically, the Examiner states the following on page 4:

Claims 3-8, 14 and 15 are interpreted as encompassing a polynucleotide sequence comprising an antisense strand which is able to hybridize to a nucleotide sequence of element a) or b) of Claim 3, and which also encodes a polypeptide having the same biological function or activity as the RL5 protein of SEQ ID NO:2 or residues 29-213 of SEQ ID NO:2.

In addition, the Examiner states the following on page 5:

However, Applicants have not demonstrated any functional activity for the RL5 protein of SEQ ID NO:2, for example, that the RL5 protein would directly or indirectly transduce a cellular signal in binding to the NKG2 receptor. Further Applicants have not even isolated an antisense polynucleotide sequence with hybridizing capability much less one that also encodes a polypeptide having the same biological properties of RL5. (emphasis added).

Accordingly, Applicant regard the Examiner's reject is based on two grounds: (a) lack of description for biological function; and (b) lack of description for antisense sequences.

Lack of Description for Biological Function

To expedite the prosecution of the above referenced application, Claim 3 as amended does not recite the phrase “wherein the polynucleotide encodes a polypeptide which retains the same biological function or activity as the amino acid sequence of SEQ ID NO: 2, or the amino acid sequence of 29-213 of SEQ ID NO: 2.”

However, such an amendment does not mean that Applicants believe that the specification fails to provide adequate description for biological functions.

Indeed, the Applicants' well-designed assay in the Specification teaches that the biological activity of the RL5 protein prevents the binding between the NKG2D receptor and its corresponding antibody. Applicants compare the binding of the NKG2D receptor to its antibody in the presence of

the RL5 protein (the experimental group) with that of the binding of antibody to NKG2D receptor without the presence of the RL5 protein (the control group). The results of the assay indicate that the NKG2D receptor fails to bind to its antibody in the experimental group; by contrast, in the control group the binding between the NKG2D receptor and its antibody proceeds in an uninhibited fashion. See Example 8 of Specification, page 16, line 18 – page 17, line 13. Therefore, the RL5 protein can either directly or indirectly transduce a cellular signal interfering with the binding to the NKG2D receptor and its antibody.

The assay of Example 8 describes the biological function of the claimed invention with sufficient particularity such that one of ordinary skill in the art would recognize that the Applicants were possession of the claimed invention at the time of filing.

In light of the amendments made to prong (c) of claim 3, Applicants respectfully request withdrawal of the written description rejection.

Lack of Description for Antisense Sequences

To expedite the prosecution of the above referenced application, Claim 3 as amended does not recite the phrase “wherein the polynucleotide encodes a polypeptide which retains the same biological function or activity as the amino acid sequence of SEQ ID NO: 2, or the amino acid sequence of 29-213 of SEQ ID NO: 2.”

As a general matter, Applicants submit that claims as amended satisfy the written description requirement of § 112, first paragraph. Following the Examples set forth in the Amended Written Description Guidelines, in the present claims of the instant invention, support in the description for only one nucleotide sequence species, i.e. SEQ ID NO: 1 and one amino acid sequence, i.e. SEQ ID NO: 2, is sufficient to place the Applicants in possession of a broader genus of nucleotide sequences of claim 3. Utilizing hybridization techniques under stringent conditions to identify properties, attributes, or features of those nucleotide sequences within the genus of claim 3 of the instant invention (i.e. those nucleotide sequences which hybridize under stringent conditions to the nucleotide sequence encoding the polypeptide SEQ ID NO: 2 or 29-213 of SEQ ID NO: 2, of the complement thereof) is akin to the method of utilizing percent identity techniques to identify properties, attributes, or features of those nucleotide sequences within the claimed, written description-compliant genus of Example 11, Claim 1 (i.e. those nucleotide sequences that encode a

polypeptide with at least 85% amino acid sequence identity to SEQ ID NO:2). See Amended Written Description Guidelines, Example 11, claim 1. In essence, hybridization under stringent conditions is simply an alternative mechanism to percent identity for claiming a genus scope of comparable breadth, i.e. a genus of nucleotide sequences with a genus-specific set of common properties, attributes or features. In support of this position, the guidelines further teach that hybridization under stringent conditions requires a high degree of structural complementarity between hybridized sequences, resulting in many nucleotides in common with the hybridizing sequence. See Amended Written Description Guidelines, Example 11, claim 1.

In addition, the Amended Written Description Guidelines also indicate that had the Example genus claim been drafted in a manner nearly identical to that of Claim 3's prong (c) of the instant invention (and thus without language of activity), "the disclosure of [a nucleotide sequence] combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions [to the nucleotide sequence]." See Amended Written Description Guidelines, Example 6, claim 6.

Therefore, Applicants believe that Claim 3 as amended is in condition for allowance and respectfully request withdrawal of the written description rejection.

As an additional matter, Applicant respectfully point out that the publication US 2007/0275419 shows an error of SEQ ID NO: 1 as a 48-nucleotide DNA where SEQ ID NO:1 should be a 720-nucleotide DNA. This sequence inconsistency is likely due to a mistake of prior counsel at Dorsey & Whitney LLP where only 48-nucleotide of SEQ ID NO:1 was submitted in the petition to revive on August 9, 2006. Applicant respectfully request the Examiner's attention that the SEQ ID NO:1 should have 720 nucleotide when a patent is issued from the subject application.

CONCLUSION

Applicants believe that this response has been timely submitted and all pending claims are in condition for allowance. Applicants believe that no additional fees are necessary at this time. However, in the event that Applicants are incorrect in their assumption, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 24569-714.831).

Respectfully submitted,

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